

REMARKS

The Office Action of December 11, 2010 presents the examination of claims 44-46, claims 1-39 having been canceled, and claims 47-53 being deemed withdrawn from consideration follow restriction of the claims.

Restriction/election

The elected subject matter is directed to compositions/formulations of gancyclovir. The withdrawn subject matter relates to methods of making the gancyclovir as claimed or utilized in said formulations. Rejoinder of the withdrawn claims pursuant to MPEP § 821.04 is anticipated by Applicants should the present composition/formulation claims be found allowable.

Rejection over prior art

Claims 44-46 are deemed unpatentable under 35 USC § 103(a) as being unpatentable over Smith '475 in view of Harris '258 and Mueller '776. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the Examiner fails to establish *prima facie* obviousness of the claimed invention. At least the combination of cited references fails to disclose or suggest at least one feature recited in the claims.

In essence, the Examiner's position is that the gancyclovir prepared as described in claim 47 is the same as the gancyclovir disclosed in Smith '475 and that the subsequent dissolution in saline or glucose solution and packaging into a tri-layer bag is obvious given that these are allegedly typical formulation and dispensing options in the art.

However, the Examiner's supposition that the gancyclovir of the invention is the same as that disclosed by Smith '475 is incorrect. At page 6, lines 22 and following, the present specification describes that interaction of glucose with alkaline residuals in gancyclovir produces furfurals that react with the gancyclovir to produce degradation products.

Stabilization of the glucose solutions of gangcyclovir by preparing the gangcyclovir free from alkaline residuals is shown in the working examples.

On the other hand, as explained in the attached Declaration of Mr. Perillo, the gangcyclovir of Smith '475 (representing the state of the art at the time the present invention was made), did not suggest the alkaline pH of a solution of gangcyclovir (*see, e.g.*, paragraph 18 of the Declaration and that the pH of the final solution in Smith '475 is above 7 (col. 12, line 64)). Thus, the gangcyclovir preparations of the prior art were susceptible to degradation for reasons not apparent to the skilled artisan who reads the references cited by the Examiner.

In view of the above, there is a plain point of distinction of the invention over the prior art in that the gangcyclovir is made into a neutral to acidic solution prior to packaging. This feature is recited in the independent claims 44 ("free acid form, free from alkaline residues") and 54 ("pH ranging from 3.0 to 6.9") but is not disclosed or suggested in the combination of references cited by the Examiner.

Thus, the Examiner fails to establish *prima facie* obviousness of the present invention and the instant rejection should be withdrawn.

Furthermore, the present invention provides a result that is not expected by one of ordinary skill in the art who reads Smith '475 in view of Harris '258 and Mueller '776, and serves as objective evidence of unobviousness of the present invention.

The attached Declaration of Mr. H. Perillo establishes that the state of the art at the time the invention was made was such that solutions of gangcyclovir for administration were of high pH, and that they were unstable in the absence of refrigeration. Mr. Perillo's testimony establishes that, in contrast, by eliminating alkaline residues from the crystalline gangcyclovir that is dissolved for administration, the stability of the solution of gangcyclovir is greatly and unexpectedly enhanced.

Applicants submit that the evidence of unobviousness of the present invention of the Perillo Declaration provides another, independent reason for withdrawal of the present rejection.

The favorable actions of withdrawal of the present rejection over prior art and allowance of all of the pending claims are respectfully requested.

Should there be any outstanding matters that need to be solved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned bellow, to conduct an interview in an effort to expedite prosecution in the connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.R.F. §§1.16 or 1.14; particularly, extension of time fees.

Dated: June 11, 2010

Respectfully submitted,

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Attachment: Perillo Declaration